

K982670

OCT 2 1998

510(k) Summary

Proprietary Name: Contemporary Acetabular Component

Common Name: All Polyethylene Acetabular Cup

Classification Name and Reference: CFR 888.3350

This device is a component of a hip joint, metal/polymer, semi-constrained cemented prosthesis.

Proposed Regulatory Class: Class II

Device Product Code: OR(87) JDI

For information contact: Frank Maas
Manager, Regulatory Affairs
Howmedica Inc.
359 Veterans Boulevard
Rutherford, NJ 07070
Telephone: (201) 507-7875
Fax: (201) 507-6870
Date Summary Prepared: 7/31/98

The Contemporary Acetabular Component is a polyethylene cup that is intended to replace the bearing portion of the acetabulum in primary or revision total hip arthroplasty. This cup is designed to be cemented into the acetabulum.

The Contemporary Acetabular Component is available in outer diameters of 38 to 80mm in two millimeter increments. These cups are manufactured from Ultra High Molecular Weight Polyethylene which conforms to ASTM F-648.

The substantial equivalence of the Contemporary Acetabular Component is based on an equivalence in intended use, materials, design, operational principles, and relative indications and contraindications to Howmedica's Premise All Polyethylene Cup (K912426) and Johnson & Johnson's Ultima™ All Polyethylene Cup (K924115).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT 2 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Frank Maas
Manager, Regulatory Affairs
Howmedica Inc.
Pfizer Medical Technology Group
359 Veterans Boulevard
Rutherford, New Jersey 07070-2584

Re: K982670
Trade Name: Contemporary Acetabular Component
Regulatory Class: II
Product Code: JDI
Dated: July 31, 1998
Received: July 31, 1998

Dear Mr. Maas:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

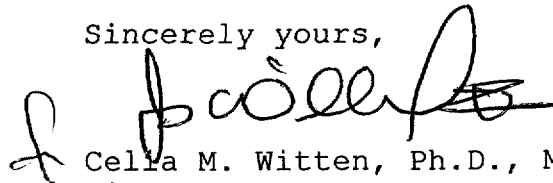
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in dark ink, appearing to read 'C. Witten', is written over the typed name.

Cella M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K982670

Device Name: Contemporary Acetabular Component

Indications for Use:

The Contemporary Acetabular Component is intended to be used to replace the bearing portion of the acetabulum in primary or revision total hip arthroplasty. This component is designed to be cemented into the acetabulum.

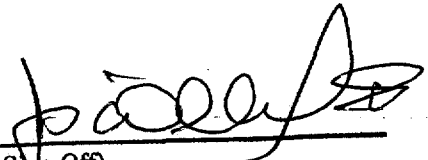
(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use yes OR
(Per 21 CFR 801.109)

Over-The-Counter Use No

(Optional Format 1-2-96)



(Division Sign-Off)
Division of General Restorative Devices

510(k) Number K982670